UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,518	01/28/2002	Toshio Ota	14897-097001/H1-107PCT1-U	5393

26161 7590 06/02/2004

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/058,518	OTA ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *9,10 and 13-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11,12 and 18-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Paper filed 5 May 2004. Applicant's amendment of claims 1, 2, 11 and 12 is acknowledged. Applicant's addition of new claims 18-62 is acknowledged. Claims 1-8, 11-12, 18-62 are under examination.

Withdrawal of Objections and Rejections

The objections and/or rejections not explicitly restated or stated below are withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8, 11-12, 18-62 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gmerek *et al.* (Genbank Accession U13395). Gmerek *et al.* teach the HHCMA56 cDNA that is 98.6% identical to SEQ ID NO: 1 from positions 578-2052. The sequence taught by Gmerek would hybridize to SEQ ID NO: 1 and encode fragments of SEQ ID NO: 2. The nucliec acid of Gmerek *et al.* was cloned from a hippocampus library, therefore would have been replicated in bateria cells and contained in a cloning vector.

Furhtermore, Applicant states "the results of homology search showed that the query clone was identical to the helix clone "C-T2RP3001495". In addition, it was also revealed that

the query clone is identical to the gene for Hs.519 Human oxidoreductase (HHCMAS6) of Unigene." Thus, the invention is anticipated by helix clone "C-T2RP3001495" and the gene for Hs.519 Human oxidoreductase (HHCMAS6).

Gmerek *et al.* teach the product of the nucliec acid as an oxidoreductase and provide the translation of the peptide seqeuence. Thus, the protein product of the nucleic acid was known as an oxidoreductase and is identical to the protein product of the claims. In the alternative, a person of ordinary skill in the art would have been motivated by the teachings of Gmerek *et al.* to produce the oxidoreductase. The amino acid sequence of the protein in an inherent property of the protein itself, therefore, despite the mistakes of the prior art as to the exact sequence, the protein was known, which inherently possessed the amino acid sequence that is now corrected by Applicant.

Applicant argues that the HHCMA56 cDNA of the prior art was translated out of frame and therefore encodes a different protein. This argument has been fully considered but is not persuasive. As stated above, the actual physical nucleic acid molecule was known in the prior art. Gmerek *et al.* made a mistake in reading the sequence, however, the actual molecule is the same and thus, the protein product of the molecules are indentical. Applicants have merely corrected the nucleic acid sequence and provided new information for a known molecule. The sequence is an inherent property of the nucliec acid and depsite the mistake in reading the molecule, the nucliec acid taught in the prior art is identical to that of the present invention. Thus, the reference clearly anticipates the invention as recited in the claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 5-8, 11-13, 20-23, 27-29, 32-34, 38-40, 43-45, 49-51, 54-56, and 60-62 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility which is specific and substantial, or a well-established utility. The claims are drawn to a transformant that reads upon a transgenic animal. The claim recites no specific phenotype associated with any transgenic animal. However, knowledge of a phenotype is required before an animal can be used to provide a model for a disease. Because no animal is disclosed by specific phenotype, and no specific animal model is claimed, the claimed animals can have no specific utility or well-established utility. No one skilled in the art can use the claimed animals in a manner that provides immediate benefit to the public, because no immediately useful characteristic of the claimed animals is disclosed. Additional research would be required to determine the phenotype of each mutant animal in order to render each animal useful. If further research is required to establish or confirm a real world context of use for an invention, that invention lacks a substantial utility. Furthermore, the asserted utility of an animal model for a systemic disease can apply to other animals not encompassed by the claims. Therefore the asserted utility is not considered a "specific" utility, *i.e.* it is not specific to the animals claimed. Because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5-8, 11-13, 20-23, 27-29, 32-34, 38-40, 43-45, 49-51, 54-56, and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a transformant that reads upon a transgenic animal. Neither the claim nor the specification discloses the phenotype of the claimed animal. In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species has been described by complete structure. It is not realistic to expect that the complete structure of a transgenic animal could be described, therefore the inquiry required by this portion of the written description guidelines is interpreted to be whether the phenotypic consequences of altering the genotype have been described.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (571) 272-0959. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for regular communications to the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
May 27, 2004

SKS

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER